

MAY 13 1999

K983728

Summary of Safety and Effectiveness

Device Name: Lorenz IMF Screw

Classification Name and Reference: Screw, Fixation, Intra osseous (21 CFR 872.4880)

Intended Use: The Lorenz IMF Screw is intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla and/or the mandible.

Device Description: The bone screw for maxillomandibular fixation is 1.7mm in diameter and lengths may range from 8mm - 20mm. The head has a relief groove which may or may not have a hole in which a wire or elastic bands can be wrapped around the screws which are temporarily implanted in the maxilla and mandible. The tip of the screw is designed so that a predrilled hole is not required, but may be used.

Potential Risks:

- Nonunion or delayed union which may lead to breakage of device.
- Metal sensitivity or allergic reaction to a foreign body.
- Pain, discomfort or abnormal sensations due to the presence of the device.
- Nerve damage due to trauma or improper placement of the device.
- Other conditions brought on by the surgical procedure including skin irritation and infection.
- The device may bend, loosen, or fracture while implanted.
- Biomechanical complications due to improper positioning of the mandibular condyle.

Substantially Equivalent Devices: The device is believed to be substantially equivalent to Leibinger IMF Screw K963030.

Sterility Information: The device is being labeled nonsterile. Sterility recommendations are included in the package insert.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 13 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Diana Preston
Regulatory Affairs Specialist
Walter Lorenz Surgical, Incorporated
1520 Tradeport Drive
Jacksonville, Florida 32218-2480

Re: K983728
Trade Name: Lorenz IMF Screw
Regulatory Class: II
Product Code: DZL
Dated: February 12, 1999
Received: February 16, 1999

Dear Ms. Preston:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

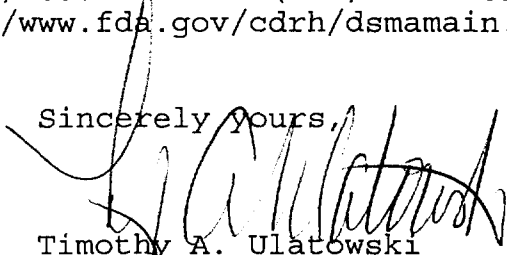
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: Lorenz IMF Screw

Indications For Use: The Lorenz IMF Screw is intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla and/or the mandible.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K983728

Prescription Use ☒
(Per 21 FR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)